



Pacebiotech Pharma (India) Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Ondican 4 Injection (Ondansetron Hydrochloride Injection IP 2mg/ml)		
Batch No.	25AF081A	A.R. No.	FP250157
Batch Size	100200 Amps	Sample Quantity	60 Nos
Mfg. Date	06/2025	Date of Testing	04/06/2025
Exp. Date	05/2027	Date of Release	20/06/2025
Reference Batch No	25AF081	MFG. Lic. No.	N-MB-2023/263

Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution	Complies
3.	pH	Between 3.3 to 4.0	3.91
4.	Related Substance Any other Impurity Total Impurity	NMT 0.2% NMT 1.5%	Complies Complies
5.	Extractable Volume	NLT 2.0 ml	2.0 ml
6.	Bacterial Endotoxins	NMT 9.9 Endotoxin unit per mg of Ondansetron	Less than 9.9 Endotoxin unit per mg of Ondansetron
7.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
8.	Sterility	Should be complies	Sterile
9.	Assay: Each ml contains: Ondansetron Hydrochloride IP		